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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,841	01/12/2001	Susan Dobbs	PCS 10348ADAM	1916

7590

07/27/2005

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EXAMINER

BROWN, TIMOTHY M

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 07/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/759,841	Applicant(s) DOBBS ET AL.	
	Examiner Timothy M. Brown	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2005 and 11 May 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3-5 and 12-21 is/are pending in the application.
- 4a) Of the above claim(s) 12-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-5 and 16-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

This Non-Final Office Action is responsive to (i) the Amendment and Reply mailed January 10, 2005 and (ii) the Response to Non-Compliant Amendment mailed May 11, 2005.

The status of the claims is as follows:

Claims 1, 3-5 and 16-21 are under examination.

Claims 12-15 are withdrawn.

Claims 2 and 6-11 have been canceled.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

***Claims 1, 3-5 and 16-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.***

Claim 1 is indefinite in that it provides that the agent is “capable of modulating.” This language does not particularly point out and distinctly claim the invention because it is unclear whether the claim requires an agent that actually modulates the interaction of CCR5 and gp120; the claim only provides that the agent is “capable of” this activity. Therefore, claim 1 fails to particularly point out and distinctly claim the invention. Note that claim 16 also recites “capable of” and is therefore is indefinite for the same reasons as claim 1.

Claim 1 is also indefinite for omitting an essential step. Claim 1 is drawn to a method for identifying agents that modulate the low affinity binding of CCR5 and gp120 comprising

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incubating a test agent with CCR5 and gp120, adding an anti-gp120 antibody to the reaction mixture, and determining whether the agent modulates the interaction of CCR5 and gp120.

However, the method fails to perform a measuring step wherein at least one of the agent, CCR5, gp120 and anti-gp120 antibody are actually measured. Without collecting some data on the affect of the agent on the reaction mixture, one skilled in the art could not possibly determine whether the agent has the effect of modulating the CCR5/gp120 interaction. Accordingly, claim 1 is indefinite for omitting a measuring step wherein the effect of the agent is determined using one of the components of the reaction mixture.

Claim 1 is also indefinite in the recitation of “modulating” in line 1, and “modulates” in line 10. This language makes the claim indefinite because is unclear whether “modulating” refers to inhibiting, or enhancing, the interaction between CCR5 and gp120. This is particularly true given that the claim does not indicate which reaction mixture components are being used to determine whether the agent interrupts the interaction CCR5/gp120.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

***Claims 1, 3-5 and 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allaway et al. (US 6,107,019) in view of Masuho et al. (US 5,695,927).***

The invention is drawn to a method for identifying agents that modulate the low affinity binding of CCR5 and gp120 comprising contacting a test agent with CCR5 and unlabeled gp120 to form a first reaction mixture, adding an anti-gp120 antibody to the first reaction mixture to form a second reaction mixture, and determining whether the test agent modulates the interaction of CCR5 and gp120.

Allaway et al. disclose many features of Applicants' method including fixing CCR5 to a solid phase, contacting a test agent with the fixed CCR5 and unlabeled gp120, and determining whether the agent modulates the interaction of CCR5 and gp120 (col. 1, lines 34-36; and col. 9, lines 21-49). Allaway et al. do not expressly teach adding an anti-gp120 antibody to the first reaction mixture to form a second reaction mixture. However, Masuho et al. teach labeled anti-gp120 antibodies that are capable of detecting the presence of gp120 (see e.g. col. 22, line 15). At the time of Applicants' invention, it would have been obvious to modify Allaway et al. to include Masuho et al.'s labeled gp120 antibody in its assay method since this combination would provide for the rapid detection of gp120 bound to Allaway et al.'s solid phase CCR5. One skilled in the art would have a reasonable expectation of success using this method given that

immunoassay ligands, and detectable labels, are readily interchangeable. It is also worth noting that it would have been obvious to modify Allaway et al. and Masuho et al. to include secondary and tertiary antibodies, as well as the various labels recited in the claims. This results because these limitations simply provide different assay formats which are simply a matter of choice to one skilled in the art.

### ***Response to Arguments***

Applicants' arguments regarding the art rejections under Wu et al. and LaRosa are moot in view of the new art rejections presented above.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tim Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Timothy M. Brown  
Examiner  
Art Unit 1648

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TMB  
7/23/05



MARY E. MOSHER, Ph.D.  
PRIMARY EXAMINER